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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,228	03/23/2004	Atsushi Sogabe	226749	3077

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EXAMINER

SLOBODYANSKY, ELIZABETH

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/807,228	Applicant(s) SOGABE ET AL	
	Examiner Elizabeth Slobodyansky, PhD	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 08/799,897.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/23/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is a divisional of reissue application 09/940,941, now allowed, that is a reissue of 08/799,897 issued as US Patent 6,080,553.

The specification and the abstract have been amended on March 23, 2004 to replace pl 3.5 with pl 4.5. Claims 1-23, from the issued patent, have been canceled and claims 24-28 have been added.

The Declaration under 37 CFR 1.132 by Dr. Atsushi Sogabe filed February 4, 2004 has been entered. The Declaration provides evidence that creatine amidinohydrolase of the invention, including the species encoded by plasmids pCRH273M1, pCRH273M2 and pCRH273M3, has pl 4.5 and not pl 3.5 as claimed in US Patent 6,080,553.

It is noted that Original Patent has been surrendered February 4, 2004 in reissue application 09/940,941.

It is noted that the computer readable form filed March 23, 2004 contained an error such that nucleotide at position 1199 was shown as "C" instead of "A". This CRF was replaced with a CRF transferred from the parent application 08/799,897 as requested by Applicants in "Communication regarding Sequence Listing" filed March 23, 2004 (paragraph bridging pages 1-2). The Sequence Listing of the transferred CRF is

100% identical to the Sequence Listing printed in US 6,080,553 and to the Sequence Listings in CRFs of 08/799,897 and 09/940,941.

Claims 24-28 are pending.

Specification

The disclosure is objected to because of the following: The specification describes amidinohydrolase from *Alcaligenes faecalis* TE3581 (FERM P-14237) having the amino acid sequence of SEQ ID NO:1 and encoded by SEQ ID NO:2. However, SEQ ID NO:2 does not encode the sequence of SEQ ID NO:1 but encodes the sequence that differs therefrom at position 145. while nucleotides 433-435 of SEQ ID NO:2 (GAC) encode Asp, SEQ ID NO:1 indicates Glu not Asp at position 145.

Clarification is required.

Applicant is notified that any subsequent amendment to the specification and/or claims must comply with 37 CFR 1.121(b).

Claim Objections

Claim 24, with dependent claims 25-28, is objected to because of the following: It appears that "for creatine" is missing after "Km values" on line 6 (clause "(ii)").

Appropriate correction is required.

Applicant is notified that any subsequent amendment to the specification and/or claims must comply with 37 CFR 1.121(b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Furukawa et al.

Furukawa et al. (US Patent 5,932,466) teach amidinohydrolase from *Alcaligenes* sp. KS-85 (FERM BP-4487) having the amino acid sequence of SEQ ID NO:2 and a nucleic acid sequence encoding thereof, including SEQ ID NO:1. SEQ ID NO:2 disclosed by Furukawa et al is 100% identical to SEQ ID NO:1 of the instant invention. Therefore, the amidinohydrolase of the instant invention and the amidinohydrolase disclosed by Furukawa et al are identical enzymes with identical characteristics that are inherent. Said characteristics include the properties recited in claims 25-28.

It is noted that the claims are drawn to a method not a product. Thus, claims 24-28 are drawn to a method of mutating a known sequence. There are several known methods for mutating a protein such as chemical and irradiation mutagenesis, random and site-directed mutagenesis, etc. These methods are enabled and widely used in the art. It is noted that claims 24-28 do not require a mutation at the specific position. The claims do not comprise the specific step(s) that would necessarily result in an amidinohydrolase with a lower K_m . The claimed method requires only screening that may or may not be successful. Therefore, claims 24-28 are drawn to a known and

enabled method of mutating a known sequence. Such method is obvious for the reasons discussed above.

Furthermore, Furukawa et al teach the desirability of obtaining amidinohydrolase with low K_m for creatine (e.g., column 1, lines 15-32). It is core knowledge in enzymology that the lower K_m renders the reaction more specific. Therefore, an amidinohydrolase with a lower K_m renders the determination of creatine more sensitive.

It would have been obvious for one of ordinary skill in the art at the time the invention was made, to mutate a nucleic acid encoding a known amidinohydrolase of SEQ ID NO:2 and screen the encoded proteins for amidinohydrolase activity with lower K_m values for creatine. One of ordinary skill in the art would be motivated to do so in order make a more sensitive reagent for determining creatine in a sample. One of ordinary skill in the art would have a reasonable expectation of success because the difference between the requisite range of K_m values 3.5-10.0 mM and K_m for creatine of the instant enzyme is only slightly higher than the experimental error. The instant inventors disclose K_m for creatine of 15.2 mM (column 12, line 40, Table 7) whereas Furukawa et al teach K_m for creatine of 13 mM for the same amidinohydrolase (column 6, lines 35-37). Therefore, one of ordinary skill in the art would have a reasonable expectation of success in obtaining amidinohydrolase with K_m below 10 mM by mutating the gene encoding amidinohydrolase disclosed by Furukawa et al. One of ordinary skill in the art would have a reasonable expectation that the physico-chemical properties of the parent amidinohydrolase recited in claims 25-28 would not change.

Applicant is notified that any subsequent amendment to the specification and/or claims must comply with 37 CFR 1.121(b).

Applicant is reminded of the continuing obligation under 37 CFR 1.56 to timely apprise the Office of any litigation information, or other prior or concurrent proceeding, involving Patent No. 6,080,553, which is material to patentability of the claims under consideration in this reissue application. This obligation rests with each individual associated with the filing and prosecution of this application for reissue. See MPEP §§ 1404, 1442.01 and 1442.04.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky, PhD whose telephone number is 571-272-0941. The examiner can normally be reached on M-F 10:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, PhD can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Elizabeth Slobodyansky, PhD
Primary Examiner
Art Unit 1652